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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,522	06/04/2001	Stephen M. Allen	BB-1315	5209
7590	07/28/2004		EXAMINER	
Gregory J Feulner E I du Pont de Nemours & Company Legal Patents Wilmington, DE 19898			BUI, PHUONG T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,522

Applicant(s)

ALLEN ET AL.

Examiner

Phuong T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/8/01</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's amendment and restriction election filed May 20, 2004. Applicant elected Group I and Invention B (SEQ ID NO:3 and 4) without traverse. Claims 24-33 are pending and are examined in the instant application. This restriction is made final.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See pages 8 and 19, for example.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 24-25 and 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "a polypeptide having SNF1 activity". Neither the state of the art nor Applicant's disclosure defines what SNF1 activity encompasses. While "SNF1" may be an art-recognized term and its activity is inherent in the complete protein, one skilled in the art would not be able to determine from a population of sequences having less than 100% sequence identity which would

have SNF1 activity, as such is not defined. Accordingly, one would not be reasonably apprised of the metes and bounds of the claimed invention based upon said recitation.

Claim Rejections - 35 USC 101 Utility

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 24-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. The claimed invention lacks substantial utility because Applicant does not teach how the claimed invention can be used to achieve a real-world use. Applicant states "The SNF1 gene encodes a 72 kDa serine and threonine protein kinase whose activity is down regulated by the availability of glucose" (p. 1) and "SNF1 act[s] antagonistically to control glycogen accumulation" (p. 2). While glucose is an important plant component, it is unclear how Applicant's SNF1 polynucleotide should be used to regulate glucose or glycogen in a manner that would be beneficial to the public and result in a useful outcome. Applicant further indicates "These genes may be used in plants to control carbon and nitrogen partitioning pathways during plant growth and development" and "the availability of nucleic acid sequences encoding all or a portion of SNF1... regulatory proteins would facilitate studies to better understand the mechanism of catabolite repression in plants and could provide genetic tools to enhance or otherwise alter the accumulation of carbohydrates, lipids and proteins during plant growth and development" (p. 2). Again, Applicant provided no guidance as to how the claimed SNF1 polynucleotide should be used to control carbon and nitrogen partitioning

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pathways in a useful manner. For example, if SNF1 in a plant is overexpressed and the plant's glycogen level is decreased, what plant traits would be affected, and how? What does carbon and nitrogen partitioning ultimately lead to—more vegetative growth, disease resistance, increase of lipids or proteins in plant storage organs? It is apparent that further research is required before the claimed polynucleotide would be of benefit to the public. However, the courts have decided that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use lacks substantial utility.

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (Brenner v. Manson, 383 U.S. 519 (1966)).

Thus, while regulating certain genes for certain traits would provide substantial benefit to the public, the claimed invention is not refined and developed to the point where specific benefit exists, as no guidance is provided as to how SEQ ID NO:3 should be used to alter any specified plant trait. Accordingly, the claimed invention lacks substantial asserted utility.

Additionally, there is no well-established utility for SEQ ID NO:3 and a sequence encoding SEQ ID NO:4. SEQ ID NO:3 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed sequences lack utility (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claim Rejections - 35 USC § 112, first paragraph

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7. Claims 24-33 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Additionally, claims reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining SNF1 activity, however such activity is defined. Applicant provided no working examples or further guidance as to which region(s) of SEQ ID NO:3 are conserved domains necessary for protein activity. While one skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated without undue experimentation. Accordingly, the claimed invention is not enabled.

8. Claims 24-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims reciting less than 100% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass SNF1 proteins from other species. The implication is that there is a gene and a protein other than that disclosed which exists in

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nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:3 isolated from *Zea mays*. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants and allelic variants of other *Zea mays* plants, or the structure of SNF1 proteins from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

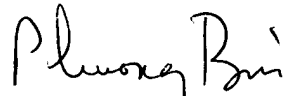
Remarks

9. No claim is allowed. SEQ ID NO:3 and a nucleotide sequence encoding SEQ ID NO:4 are free of the prior art. The closest prior art teaches a sequence isolated from *Oryza sativa* having 89% sequence identity with SEQ ID NO:4 using Applicant's alignment method and default parameters as set forth in the claims (Table 4, p. 21; and Takano et al., Mol. Gen. Genetics, vol. 260(4)388-394 (Applicant's IDS)). It is noted that the polynucleotide sequence encoding SEQ ID NO:4 has 89.9% sequence identity with the Takano sequence when using Office alignment method and default parameters. The Takano sequence is considered to be excluded from Applicant's claimed invention.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Phuong T. Bui
Primary Examiner
Art Unit 1638
7/14/04

07/14/04